

Serial No.: 10/757,159  
Examiner: Laura C. Schell  
Group Art Unit: 3767

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### STATUS OF CLAIMS

Claims 11-20, 22, and 23 are presently pending and under examination.

Applicant has amended claim 18. Support for the amendment to claim 18 is found in the specification and claims as originally filed. Applicant submits that no new matter has been added.

### REMARKS

Applicant acknowledges that in response to Applicant's response filed May 14, 2007, the Examiner has withdrawn her rejection of claims 11, 12, 17 under 102(b) as being anticipated by Hicks (U.S. Patent No. 2,825,134). The Examiner has also withdrawn her rejection of claims 13-16 under 103(a) as being unpatentable over Hicks. With respect to the remaining rejections, please consider the following remarks.

#### Rejection Under 35 U.S.C. §102(b) - Hicks

Claims 18-20, 22, and 23 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hicks (U.S. Patent No. 2,825,134).

In the Office Action, the Examiner takes the position that Hicks discloses the claimed coupling system for use with a tube of a syringe, comprising: a housing for coupling to the tube of the syringe; a drive mechanism disposed within the housing; a mixing member for coupling to the drive mechanism, the mixing member for extending into the tube of the syringe and being rotatable within the tube of the syringe to mix and deliver an injectable from the tube of the syringe; and an actuator coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the mixing member.

In response, Applicant respectfully traverses the rejection over Hicks. Applicant submits that the invention of claim 18, as amended, is not anticipated by Hicks. Applicant draws the Examiner's attention to the mixing member of Hicks for the mixing of dental impression materials encased within a chamber ("the inner end of the rod 21 that is within the inner casing 1 has a mixing element 22 secured thereto" (col. 2, lines 70-72). *No mixing occurs beyond this inner casing 1.* As discussed in Hicks (see Fig. 1 of Hicks), once the dental material is mixed by mixing element 22 consisting of mixing blades 24, the material is "discharged through the

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needle-like end 39 of the nozzle 37 for depositing the impression material accurately and solidly in a cavity or around the necks of the teeth.” (col. 3, lines 70-75). Applicant has amended claim 18 to clarify that the mixing member “extends into the tube of the syringe.”

Thus, Hicks does not teach the various features of independent claim 18. For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978). The Hicks reference fails as an anticipatory reference at the very least because it fails to disclose a “mixing member for coupling to the drive mechanism, the mixing member for extending into the tube of the syringe and being rotatable within the tube of the syringe.” Rather, in the Hicks device, the mixing element 22 does not extend into the tube of the needle-like end 39; and the mixing element 22 is not rotatable within the needle-like end 39 and is only mixed within the inner casing 1.

Since the reference does not disclose all of the features of independent claim 18, Applicant states that Hicks fails as an anticipatory reference and respectfully requests that the Examiner reconsider and withdraw the rejection over Hicks. Claims 19, 20, 22, and 23 depend directly on claim 18 and contain additional distinguishing features. The rejection of those claims fails at least because of the fundamental defect discussed above with respect to independent claim 18. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 102(b) as anticipated by Hicks.

#### Rejection Under 35 U.S.C. §102(b) – Schwartz-Feldman

Claims 11 and 17 are rejected as being anticipated by Schwartz-Feldman (U.S. Pat. No. 5,501,371).

In response, Applicant respectfully traverses the rejection over Schwartz-Feldman. Applicant submits that the invention is not anticipated by the disclosures of Schwartz-Feldman. Rejected claim 11, from which rejected 17 depends, is directed to the following:

A driving system for use with an injector system, the injector system comprising: a housing defining a lumen and having an output end and a driving system connection end; a needle assembly coupled to the output end of the housing for coupling to a needle; and ***a mixing member extending through the lumen from the driving system connection end to at least the output end;*** and

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the driving system comprises:  
a drive mechanism;  
an actuator coupled to the drive mechanism to actuate the drive mechanism; and  
a rotatable interfacing member coupled to the drive mechanism for coupling with  
the mixing member to rotate the mixing member when the interfacing  
member is driven by the drive mechanism, *wherein the mixing member is  
rotatable in the needle assembly and the lumen.*

The Schwartz-Feldman reference fails as an anticipatory reference because it fails to teach all of the claimed features of claim 11. For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

For example, Schwartz-Feldman does not teach *"a mixing member extending through the lumen from the driving system connection end to at least the output end."* It does not teach that *the mixing member is rotatable in the needle assembly and the lumen.*

To support the rejection, the Examiner states that Schwartz-Feldman discloses an "injector system comprising...a needle assembly (84) coupled to the output end of the housing (coupled at 36) for coupling to a needle....[and] Fig. 1 discloses that the needle connects at 36 and *Fig. 1 also discloses that end portion 140a of the mixing member extends into the needle assembly [84].*" (emphasis added). However, Applicant respectfully points out that upon close inspection of Schwartz-Feldman and the passages cited by the Examiner, in particular, it becomes clear that Schwartz-Feldman does not teach all of the features of the claimed invention. Specifically, Schwartz-Feldman does not teach a mixing member that extends into the needle assembly and even if it were assumed that such were the case, it does not teach a mixing member which is rotatable in the needle assembly.

End portion 140a, which the Examiner cites as purportedly showing that the mixing member extends into the needle assembly, is not a part of the mixing means of Schwartz-Feldman's device, but rather, is a member that is attached to the casing ("mixing cylinder" 102) that holds the mixing means. The "end portion 140a" referred to by the Examiner refers to one of four "planar flanges 140a, b, c, and d" that is distal to the mixing mechanism taught in Schwartz-Feldman. ("Distal point 130 includes an annular beveled valve surface 138 and a plurality of *planar flanges 140a, b, c, and d* radially positioned about the center axis of

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cylindrical body 120. Planar flanges 140a, b, c, and d include an upper positioning tab 142a, b, c, and d and a lower stop tab 144a, b, c, and d;" col. 3, lines 62-67)(see col. 4, lines 57-60, which explains how the positioning tabs on the planar flanges help to affix a valve 138 that prevents inadvertent leakage of materials during the mixing action).

This is illustrated in Figures 1 and 7-9 of Schwartz-Feldman which show that mixing would occur in the "cylindrical body 120" of the mixer cylinder 102 and not in the distal point 130. As shown in these figures, the mixing means 26 is *proximal to, and does not extend into*, the tapered tip 84 (which the Examiner indicates reads upon the claimed "needle assembly"). That is, mixing occurs by a "mixing means 26 compris[ing] a paddle mixer 100 and a paddle mixer cylinder 102. Paddle mixer includes a circular planar head 104, a stem 106, and a plurality of paddle blades 108a, b, and c. Circular planar head 104 includes a plurality of notches 110a, b, c, and d for spatially coinciding with, and mechanically engaging the plunger inner ribs 66a, b, c, and d respectively." (Schwartz-Feldman, col. 3, lines 36-49).

The actual mixing that occurs in the operation of the device is illustrated in sequential steps in Figures 7-10. "The mixing process is initiated by partially retracting paddle blades 108a, b, and c through the process of rotating plunger 50 as depicted in FIG. 7. Plunger inner ribs 66a, b, c, and d are mechanically engaged to notches 110a, b, and c, transmitting the twisting motion placed on plunger 50 to paddle mixer 100...Continued rotation of plunger 50 results in a *spinning motion of mixing means 26 about the long axis of paddle mixer 100*. (col. 4, lines 33-42). The spinning motion does not further extend distally from the distal tip of the paddle mixer 100.

Thus, since the reference does not disclose each and every feature of the claim, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection over Schwartz-Feldman. Claim 17 is dependent directly on claim 11, and the rejection of that claim fails at least because of the fundamental defect discussed above.

#### Rejection Under 35 U.S.C. §103(a)

Claims 12-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schwartz-Feldman (U.S. Pat. No. 5,501,371) in view of Critchlow et al. (US 2003/0171712). The Examiner takes the position that Schwartz-Feldman discloses the invention of claim 12-16.

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In response, Applicant respectfully traverses the rejection and its accompanying remarks. Claims 12-16 are dependent directly on claim 11, discussed above, and the rejection of that claim fails at least because of the fundamental defect discussed above. Applicant asserts that given the deficiencies noted above with respect to Schwartz-Feldman, which is the primary reference, the combination of the disclosures of Schwartz-Feldman with the secondary reference, Critchlow et al., fails to establish a *prima facie* case of obviousness.

In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the claims as unpatentable over Schwartz-Feldman in view of Critchlow et al.

### CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

### FEES

The Office is authorized to charge any fees required, including the fee for a one-month extension of time to deposit account number 50-1047.

Respectfully submitted,



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